UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation, BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and BECTON DICKINSON AND COMPANY, a New Jersey corporation,	:	Case No. 94-105 RRM
Plaintiffs,	:	
v.	:	
CELLPRO, INC., a Delaware corporation,	:	
Defendant.	:	

DECLARATION OF DR. CHARLES HESDORFFER

DECLARATION OF DR. CHARLES HESDORFFER

I, Charles Hesdorffer, M.D., hereby declare that:

1. I am the Director of the Bone Marrow Transplant program at the College of Physicians and Surgeons of Columbia University. A copy of my Curriculum Vitae is attached as Exhibit A.

2. I am familiar with the operation and capabilities of CellPro's CEPRATE® SC stem cell concentrator, based on: (a) having read and contributed to the scientific and technical literature about its capabilities; (b) having regularly worked with the device in the course of clinical trials and studies over the last four (4) years; (c) having performed autologous stem cell transplantation procedures (under an investigator-sponsored clinical study) on at least eight (8) patients using suspensions prepared with the device; and (d) being currently involved in clinical research of therapies that utilize the device. I am also familiar with CellPro's CEPRATE® LC device and have used it in our laboratory to conduct significant amount of preclinical work.

3. At the present time, we have an ongoing gene therapy protocol involving twenty (20) patients under which stem cell suspensions produced by the CEPRATE® SC device from peripheral blood and bone marrow are utilized in autologous transplantation procedures. Thus far, seven (7) patients have been treated under this protocol.

4. Furthermore, we also have a pending tumor cell purging study using the CellPro device for autologous transplantations in patients with lymphoma, myeloma,

sarcoma, and neuroblastoma. We anticipate that sixty (60) patients will be treated under this protocol.

5. In my experience, the CellPro device is a user-friendly, computerized and self-enclosed device that gives reproducible results and for which there is a suggestion that the cell suspensions produced by it have a reduced risk of infusional toxicity. We chose the CellPro device also because we had done significant amount of preclinical work in our laboratory using the CellPro CEPRATE® LC device and further because the CEPRATE® SC device has good CD34 purification qualities. In contrast, the Baxter ISOLEX device is more time consuming and laborious to use.

6. I believe there is a compelling public interest in the continued availability, and access to, the CellPro CEPRATE® SC device.

7. The availability of CellPro's FDA-approved CEPRATE® SC device is important in testing and developing novel experimental procedures. In my experience, the ability to obtain approval for an experimental protocol from the FDA and/or hospital's or university's approval committee, is made easier if at least the stem-cell-enrichment and transplant step of that experimental procedure is performed with an FDA-approved device such as CellPro's CEPRATE® SC device.

8. Further, the fact that CellPro's device is FDA-approved facilitates patient recruitment and consent to undergo an experimental procedure where the CellPro device is used in one of the steps of that experimental procedure.

9. If the CellPro CEPRATE® SC device were to become unavailable, patients who are not eligible for a clinical study (and for whom one must then use an FDA-

approved device) would be left with only the traditional treatments such as PCT transplants which may involve undue risks of toxicity and other drawbacks.

10. In addition, the continued availability of the CellPro device is important to our ongoing clinical protocols. If the CellPro device were to become unavailable our clinical research and studies would be set back significantly. We would more than likely have to discard our already accumulated data, retrain staff with another device, and reapply for FDA and institutional clearances anew. I estimate that our efforts would be set back by up to two (2) years. Further, even if an alternative device were available, I would not be sure that it would work just as well for our purposes.

11. I also believe that there is an unquestionable benefit to be derived from keeping the CellPro device (as the only FDA-approved device) on the market as its availability would spur new and novel treatment procedures. For example, the CellPro device when modified for use with other suitable antibodies, would permit us to purify for subpopulations of stem cells which in turn may lead to novel and safe transplant procedures. In sum, the CellPro device has opened the door to new avenues of research and development and should be kept available in the interest of the public.

12. I also believe that there is a compelling public interest in keeping available the CEPRATE® LC device as none of the other companies have a comparable device. I have used the CellPro CEPRATE® LC device to conduct a significant amount of research in our laboratory relating to gene therapy. I have used the device to perform proof-of-principle tests to assure myself that a proposed human study is promising and

worth doing. If the CEPRATE® LC device were to become unavailable, it would significantly hamper my research efforts.

I further declare under penalty of perjury that the foregoing is true and correct.

Executed this 16th day of April, 1997, at New York, New York.

Charles Hesdorffer, M.D.

CURRICULUM VITAE

Date of Preparation: April 1st, 1997

PERSONAL DATA:

NAME: **CHARLES STEVEN HESDORFFER**
Birthdate: 16th December 1955
Birthplace: South Africa
Citizenship: Resident alien with green card since July 1986

ACADEMIC TRAINING:

University of the Witwatersrand Johannesburg, South Africa.	Medical Degree (MB, BCh)	1978
ECFMG	ECFMG Certificate	1978
Visa Qualifying Examination	VQE	1980
University of the Witwatersrand Johannesburg, South Africa	Master of Medicine (MMed)	1986

Thesis title for MMed degree: A retrospective multivariate analysis of abdominal aortic aneurysmectomies performed at the Johannesburg Hospital, to determine factors which might predict the development of renal failure. University of the Witwatersrand, South Africa.

New York State License Unrestricted	FLEX	1987

TRAINEESHIP:

Intern in medicine/surgery (Prof. T.H. Bothwell)	Johannesburg Teaching Hospitals Johannesburg, South Africa	1979
Medical resident (Prof. T.H. Bothwell)	Johannesburg Teaching Hospitals Johannesburg, South Africa	1981-83
Chief resident, medicine and hematology/oncology	Johannesburg Teaching Hospital Johannesburg, South Africa	1984